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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/899,381 | 07/02/2001 | Glenda C. Delenstarr | 10010760-1 | 3033 |

7590 05/19/2005

Agilent Technologies, Inc.
Legal Department, DL429
Intellectual Property Administration
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Loveland, CO 80537-0599

EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/899,381 | Applicant(s) DELENSTARR ET AL. | |
| | Examiner Bradley L. Sisson | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13,15,16 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13,15,16 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07 March 2004 has been entered.

Specification

2. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states:

[36] All patents, patent applications, and publications mentioned herein, whether *supra* or *infra*, are hereby incorporated by reference in their entirety.

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents.

3. Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In *re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of

Art Unit: 1634

the referenced document where the subject matter being incorporated may be found.
(Emphasis added)

As set forth In *Ex parte* Raible, 8 USPQ2d 1707, (BPAI, 1998)

The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree

* * *

We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. In re de Seversky, 474 F.2d 671, 177 USPQ 144, (CCPA 1973).

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Response to argument

4. At pages 4-5 of the response received 15 February 2005, applicant's representative asserts that the objection should be withdrawn as the instant application can be distinguished over *Advanced Display Systems, Inc.* The preceding argument was addressed in the Advisory Action of 24 February 2005 in that the objection to the specification was maintained, as the instant fact pattern was indistinguishable over that of *Ex parte* Raible. As no further traversal of this objection has been received, the objection has been maintained.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13, 15, 16, and 18-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. For convenience, claim 13, the only independent claim, is reproduced below.

Art Unit: 1634

13. (Currently Amended) A method of detecting the presence of an analyte nucleic acid in a sample, said method comprising:

- (a) providing a nucleic acid array comprising:
 - (i) at least one hybridization feature to which said analyte nucleic acid specifically binds under stringent hybridization conditions; and
 - (ii) at least one background feature, wherein said background feature is a polymeric composition that comprises background probes that do not specifically bind under stringent hybridization conditions to complementary nucleic acids in any target nucleic acids of said sample;
 - (b) contacting said nucleic acid array with said sample under stringent hybridization conditions;
 - (c) washing said nucleic acid array;
 - (d) detecting a hybridization signal from said hybridization feature and background signal from said background feature;
 - (e) subtracting said background signal from said hybridization signal to obtain a background corrected hybridization signal; and
 - (f) relating said background corrected hybridization signal to the presence of said analyte target nucleic acid in said sample to detect the presence of said analyte target nucleic acid in said sample;
- wherein said method is further characterized by including a target nucleic acid labeling step prior to said detecting step (d).

8. For purposes of examination, the claim, and more particularly the inserted language, has been interpreted as encompassing an embodiment where there is no binding, no matter how minimal, to any complementary sequence under any "stringent condition." Page 4 of the response asserts that support for this amendment can be found at paragraph 89 of the disclosure. For convenience, paragraph 89 of the specification is reproduced below.

Examples of empirically observed inactive probes are shown in Table 1, *infra*. In particular, these probes have been observed to bind their complementary targets very minimally, yielding minimal signal levels in hybridization assays and as such are useful as background probes in the methods of the subject invention. The probes shown in Table

Art Unit: 1634

1 are from sequences originally designed to bind human G3PDH (SEQ ID NO: 1) and P53 (SEQ ID NO: 4) targets. When the probes were allowed to hybridize to their complementary specific targets, very poor binding was observed. Subsequently, other purified targets, as well as complex pool RNA, were also observed to bind very poorly to these probes. (Emphasis added.)

As can be seen above, the background probes/features do in fact bind to nucleic acids, albeit, “minimally.” Such an aspect is in direct contrast to an embodiment now encompassed by the claims. Accordingly, the introduction of language where it states that the background feature will not bind (to any degree) to a complementary sequence is not reasonably supported by the disclosure. Accordingly, claim 13 is rejected under 35 USC 112, first paragraph, to the extent that said claim contains subject matter newly added to the application. Claims 15, 16, and 18-23, which all depend from said claim 13, fail to overcome this issue and are similarly rejected.

Conclusion

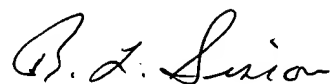
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1634

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
16 May 2005